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FILED UNDER SEAL

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PURDUE PHARMACEUTICAL PRODUCTS L.P. et al., Plaintiffs, v. ACTAVIS ELIZABETH LLC, et al., Defendants.	Civil Action No. 12-5311 (JLL) (JAD) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of motion by Plaintiffs, Purdue Pharmaceutical Products L.P., Purdue Pharma L.P., and Transcept Pharmaceuticals, Inc., (collectively "Plaintiffs") for summary judgment of no invalidity as to U.S. Patent No. 8,252,809 (hereinafter the "'809 patent"). (ECF No. 224). The Court has carefully considered the submissions made in support of and in opposition to the motion for summary judgment (hereinafter the "Motion"). Pursuant to Federal Rule of Civil Procedure 78, no oral argument was heard. For the reasons set forth below, Plaintiffs' Motion, (ECF No. 224), is **DENIED**.

I. BACKGROUND

A. General

Plaintiffs, Purdue Pharma L.P., and Purdue Pharmaceutical Products L.P., are the current holders of New Drug Application No. 022328, for sublingual tablets containing 1.75 mg and 3.5

mg of zolpidem tartrate. (Statement of Undisputed Facts ("SOUF"), ECF No. 235-1, ¶ 1). Plaintiffs market the approved drug under the tradename Intermezzo® (hereinafter referred to as "Intermezzo"). (*Id.* ¶ 2). Plaintiffs state that Intermezzo is a drug manufactured for the treatment of insomnia when middle-of-the-night awakening is followed by difficulty returning to sleep. (Compl., ECF No. 1, ¶15). There are four patents covering Intermezzo, but only the '809 patent and United States Patent No. 7,682,628 (the "'628 patent") are pertinent to this Motion.

Defendants, Novel Laboratories, Inc. ("Novel"), Par Pharmaceutical, Inc. ("Par"), and Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd (collectively, "DRL"), each filed an Abbreviated New Drug Application ("ANDA") pursuant to the Hatch-Waxman Act, seeking FDA approval to sell a generic version of Intermezzo prior to the expiration of the '809 patent. (*See generally* SOUF, ¶¶ 7-9).[1] In August of 2012, Plaintiffs responded by suing Defendants for infringement of the '809 patent.

B. Plaintiffs' Motion for summary judgment.

In this action, Defendants have asserted the defense of obviousness to invalidate the '809 patent. In response, Plaintiffs submit this Motion claiming Defendants' expert report is inadequate for a conclusion of obviousness and therefore, they are entitled to summary judgment of no invalidity. (*See generally* ECF No. 224-1). Defendants' defense of obviousness rests primarily on the expert report of Bozena Michniak-Kohn, Ph.D., (hereinafter "Dr. Michniak-Kohn"). According to Plaintiffs, in her report, Dr. Michniak-Kohn "describes the bases for her opinions in relative detail, separately describing each combination of references" and "includes 130 pages of claim charts," but does this for the '628 patent *only*. (emphasis added) (Pls.' Br., ECF No. 224 at

[1] Defendants, TWi Pharmaceuticals, Inc. and Par Formulations Private LTD., also filed an ANDA, but are not parties to the instant Motion.

2). Defendants however, argue that the inventions claimed in the '809 and '628 patents are "very similar and overlap to a substantial degree," and thus, it was only necessary for Dr. Michniak-Kohn to reference her opinions regarding the '628 patent when finding the '809 patent should be found invalid as obvious as well. (Defs.' Br., ECF No. 235 at 2). Therefore, the Court must determine whether a genuine dispute of material fact exists as to the invalidity of the '809 patent.

II. LEGAL STANDARD

Summary judgment is appropriate when, drawing all reasonable inferences in the non-movant's favor, there exists no "genuine dispute as to any material fact" and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1273 (Fed. Cir. 2010).

The moving party is entitled to judgment as a matter of law when the non-moving party fails to make "a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). However, if a reasonable juror could return a verdict for the non-moving party regarding material disputed factual issues, summary judgment is not appropriate. *See Anderson*, 477 U.S. at 242-243 ("At the summary judgment stage, the trial judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial."). With this framework in mind, the Court turns now to Plaintiffs' Motion.

III. DISCUSSION

Plaintiffs submit this Motion for summary judgment claiming that Defendants' purported obviousness defense as to the '809 patent fails as a matter of law. (Pls.' Brief, ECF No. 224 at 5). Plaintiffs' Motion is predicated on two interrelated arguments. That is, Plaintiffs argue: 1) the

Court should not consider Dr. Michniak-Kohn's expert report, as it does not satisfy the disclosure requirements of Federal Rules of Civil Procedure 26(a)(2)(B)(i) and 37(c)(1); and 2) even if Dr. Michniak-Kohn's report is considered, it contains no specificity and only the "bare assertion" that the references disclose every limitation in the asserted claims of the '809 patent rendering it obvious and thus fails to create a genuine dispute of material fact. (Pls.' Brief, ECF No. 224 at 5). The Court considers each of these arguments in turn.

A. Dr. Michniak-Kohn's expert opinion complies with Fed. R. Civ. P. 26.

As a preliminary matter, notwithstanding Plaintiffs' objection, the Court will permit and therefore consider Dr. Michniak-Kohn's expert report and opinion on the issue of invalidity as to the '809 patent for the purposes of this Motion. Although Plaintiffs herein claim that the report should not be considered as it is an improper expert disclosure, the Court is mindful that although the Federal Rules clearly contemplate the exclusion of improper expert disclosures (and the concomitant exclusion of expert testimony), the Third Circuit has cautioned that because "[t]he exclusion of critical evidence is an extreme sanction," it should not be imposed where an untimely or improper expert disclosure amounts to only a "slight deviation from pre-trial notice requirements" or occasions only "slight prejudice" to the movant. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 791 (3d Cir. 1994) (internal quotation marks and citations omitted). Instead, the remedy of exclusion should be reserved for circumstances amounting to "willful deception or flagrant disregard of a court order by the proponent of the evidence." *Id.* at 792 (internal quotation marks and citations omitted).

Relevant to this Motion, Federal Rule of Civil Procedure 26(a)(2)(B)(i) states: "if the witness is one retained … to provide expert testimony … [t]he report must contain a complete

statement of all opinions the witness will express and the basis and reasons for them." If a party fails to comply with Rule 26(a), they are not permitted "to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37. Plaintiffs here argue that Dr. Michniak-Kohn's expert report does not contain the basis and reasons for her opinion that the asserted claims of the '809 patent are invalid as obvious. (Pls.' Brief, ECF No. 224 at 5). However, Plaintiffs concede that Dr. Michniak-Kohn's report satisfies the disclosure requirements as to the '628 patent. (*Id.* at 2). It is Defendants' position that because the purported inventions of the '809 and '628 patents are very similar and that Dr. Michniak-Kohn, in her expert reports (and subsequently during her two-day deposition), proffered and supported her opinion that the asserted '809 patent claims are invalid as obvious over, amongst other things, the same prior art that renders the similar '628 patent claims obvious, her report and opinions therein are appropriate and should be considered. (Defs' Brief, ECF No. 235 at 4).

In the patent context, an expert report that merely lists a number of prior art references and concludes that one skilled in the art would find the claims obvious is deficient under Rule 26. *Innogenetics, N.V. v. Abbott Labs.,* 512 F.3d 1363, 1373 (Fed.Cir.2008). In *Innogenetics,* the Court found that the expert's report failed to "state how or why a person ordinarily skilled in the art would have found the claims ... obvious in light of some combination of those particular references." *Id.* Given this deficiency, the Federal Circuit affirmed the district court's decision to preclude the expert's conclusory testimony regarding obviousness. *Id.* at 1374.

However, here, unlike the situation in *Innogenetics,* Dr. Michniak-Kohn's report does more than merely list prior art references and provide a conclusion of obviousness. First, her report defines a person of ordinary skill in the art (referred to by Dr. Michniak-Kohn as "POSITA") to

whom the '628 patent is directed, and then states "[w]ith respect to the '809 patent, I have the opinion that a POSITA would have at least the same qualification as for the '628 patent." (Kudzin Decl., ECF No. 224-3 at 14-15). Next, Dr. Michniak-Kohn provides a detailed claim chart comparing the asserted claims of the '628 patent to the relevant prior art, (ECF No. 235-3), and explains that based on this comparison, a person of ordinary skill in the art at the time of the claimed invention would have found it obvious. (*See generally* Finn Decl., ECF No. 235-3, Ex. C). Regarding the '809 patent, Dr. Michniak-Kohn incorporates the aforementioned chart, stating "the same combinations of prior art references that render the asserted claims of the '628 patent obvious, also render the asserted claims of the '809 patent obvious." (Kudzin Decl., ECF No. 224-3 at 79). In light of the foregoing, the Court concludes that Dr. Michniak-Kohn sufficiently states how and/or why a person ordinarily skilled in the art would have found the claims of the '628 and '809 patents obvious in light of the prior art. Thus, the Court allows the report and will utilize said expert report to determine whether a genuine dispute of material fact exists as to the validity of the '809 patent.

B. A genuine dispute of material fact exists as to the obviousness of the '809 patent.

Plaintiffs argue that even if considered by the Court, Dr. Michniak-Kohn's opinions are inadequate to create a triable issue of fact as to obviousness. (Pls' Br., ECF No. 224 at 8). This Court disagrees. Under the U.S. Patent Act, an invention cannot be patented if "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). The obviousness determination turns on underlying factual inquiries involving: (1) the scope and content of prior art, (2) differences between claims and prior art, (3) the level of ordinary skill in pertinent art, and

(4) secondary considerations such as commercial success and satisfaction of a long-felt need. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966).

Dr. Michniak-Kohn opines with particularity how the '628 patent is obvious based on prior art references noted in her report, that the '628 patent and '809 patent are similar, and that these similarities make the '809 patent obvious.[2] Plaintiffs seek summary judgment based on the premise that because the '628 patent is analyzed with greater specificity and then used only as a reference for the '809 patent, Dr. Michniak-Kohn has not provided *any evidence* to create a genuine dispute of material fact. This is not the case.

First, while it is clear that "[i]n an obviousness determination, some evidentiary support must be offered beyond an expert's conclusory opinion," as the Court previously noted, Dr. Michniak-Kohn has provided an extensive comparison chart of support for her opinion that prior art references yield a conclusion of obviousness. *Rhone- Poulenc Agro, S.A. v. DeKalb Genetics Corp.*, 272 F.3d 1335, 1358 (Fed. Cir. 2001); *see also Upjohn Co. v. MOVA Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000) ("[T]here must be factual support for an expert's conclusory opinion."). Here such factual support exists as Dr. Michniak-Kohn explained the similarities and differences between the '809 patent and the '628 patent before providing an opinion that the asserted '809 patent claims are invalid as obvious over, amongst other things, the same prior art that renders the similar '628 patent claims obvious. (Defendants' Statement of Additional Material Facts ("DSAMF"), ECF No. 235-1, pgs. 27-35, ¶ 9).

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[2] Additionally, the Federal Circuit has specifically recognized that the common sense of one skilled in the art can play a role in the obviousness analysis. *See Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed.Cir.2009) (holding that "an analysis of obviousness ... may include recourse to logic, judgment, and common sense available to the person of ordinary skill [which] do[es] not necessarily require explication in any reference or expert opinion").

Upon review of the claim limitations of both the '628 patent and the '809 patent, the Court finds that a reasonable juror could interpret the claim limitations as similar. For instance, one '628 patent claim limitation states "wherein zolpidem is absorbed across a permeable membrane of the subject's oral mucosa," as compared to the '809 patent claim limitation which states "formulated for delivery of zolpidem across a subject's oral mucosa." While analyzing claim-limitation-by-limitation, Dr. Michniak-Kohn also noted differences between the '628 and '809 patents, but explained, nevertheless, why the '809 patent was obvious:

> While the '628 patent concerns the use of a solid pharmaceutical composition to treat insomnia, the '809 patent claims a solid unit dosage composition for the treatment of middle-of-the-night ("MOTN") insomnia. This indication is a subset of the broader limitations in the '628 patent related to insomnia in general. Both patents also disclose claim limitations concerning: (i) zolpidem; (ii) oral transmucosal delivery; (iii) buffers and buffering agents; (iv) rapid dissolution and entry into the blood stream; (v) and amount of zolpidem for use in the composition. The aforementioned combinations of prior art references disclose each and every limitation in the asserted claims of the '809 patent, thereby rendering them obvious.

(DSAMF, ¶ 16). To the extent '628 patent and '809 patent differ as the '809 patent is directed only towards MOTN insomnia, Dr. Michniak-Kohn references treatment of "middle-of-the-night insomnia" on numerous occasions in her report. (*See e.g.* DSAMF ¶¶ 19-20; *see also* Kudzim Decl., ECF No. 224-3 at 34-50). For example, Dr. Michniak-Kohn explicitly relies on the prior-art reference *Hernandez* to state her opinion that MOTN dosing of zolpidem (and therefore presumably the '809 patent) is obvious. (*See e.g.* Kudzim Decl., ECF No. 224-3 at 80 "Patients can retire at night without taking a hypnotic. On going to bed they can place a lormetazepam-containing wafer within reach in case they should need it. If they are unable to fall asleep they can reach for the wafer, place it under the tongue and allow it to dissolve.").

Finally, Dr. Michniak-Kohn relied on specifically identified prior-art references[3]—the same combinations that she used in rendering her opinion that the '628 patent was obvious—to support her opinion concerning the '809 patent. (*Id.* at 79). This coincides with the premise that "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006); *see also KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 127 S.Ct. 1727, 1741, 167 L.Ed.2d 705 (2007) ("To facilitate review, this analysis should be made explicit.") (*citing Kahn,* 441 F.3d at 988). That is, once a claim limitation of the '628 patent is paralleled to its comparable '809 patent claim limitation, the prior art reference relied on by Dr. Michniak-Kohn in her obviousness determination is easily identifiable. Take for example the '628 patent claim limitation:

> The method of claim 1, wherein the zolpidem or pharmaceutically acceptable salt thereof is in an amount from about 1 mg to about 5 mg; The method of claim 1, wherein the zolpidem or pharmaceutically acceptable salt thereof is in an amount from about 2 mg to about 5 mg.

(DSAMF ¶ 4-5). This limitation is comparable to the '809 claim limitation stating "wherein said effective amount is an amount of less than 1.30×10^{-5} moles[4] of zolpidem." From there, Dr. Michniak-Kohn's report explains how the prior art references *Holm* and *Merlotti* render the claims obvious to a person of ordinary skill in the art. (Finn Decl., ECF No. 235-3, Ex. C at 13).

Indeed, while Plaintiffs' arguments questioning Dr. Michniak-Kohn's conclusions may expose flaws in her opinions at trial and ultimately persuade a jury not to credit her expert report as to obviousness; the mere existence of such flaws does not warrant summary judgment. *See e.g.,*

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[3] Specifically, Dr. Michniak-Kohn's prior-art references, include: (i) *Pinney*, *Holm*, and *Merlotti*; (ii) *Pinney*, *Patat*, and *Merlotti*; (iii) *Patat*, *Zhang 2001*, *Cherukuri*, and *Tauber*; (iv) *Stanley*, *Cherukuri*, *Holm*, and *Merlotti*; (v) *Pinney*, *Patat*, and *Zhang 2001*; and (vi) *Fujii*, *Cherukuri*, and *Salva*. (Defs.' Br., ECF No. 235 at 6).

[4] 1.30×10^{-5} moles is equivalent to 5mg. (Defs.' Br., ECF No 235 at 3).

Stecyk v. Bell Helicopter Textron, Inc., 295 F.3d 408, 414-15 (3d Cir. 2002)("A party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination); *see also United States v. Mitchell,* 365 F.3d 215, 244 (3d Cir. 2004)("As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process-competing expert testimony and active cross-examination-rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.") (quoting *Ruiz-Troche v. Pepsi Cola Bottling Co.*, 161 F.l 3d 77, 85 (1st Cir. 1998)).

In sum, a reasonable juror could conclude that: 1) the asserted claims of the '628 patent are substantially similar to the '809 patent; and 2) because of these similarities, the prior art articulated by Dr. Michniak-Kohn (and incorporated by reference from the '628 patent into her opinions regarding the '809 patent) renders the '809 patent obvious and thus invalid.

IV. CONCLUSION

For the reasons set forth above, Plaintiffs' Motion for summary judgment, (ECF No. 224), is **denied**. An appropriate Order accompanies this Opinion.

/s/ Jose L. Linares
Jose L. Linares
United States District Judge

Date: October 10, 2014